DEVICES AND METHODS FOR PLACEMENT OF PARTITIONS WITHIN A HOLLOW BODY ORGAN

FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices and methods. More particularly, it relates to devices and methods for creating a partition within a hollow body organ, particularly a stomach, intestinal tract, or other region of the gastrointestinal tract, and affixing the tissue.

BACKGROUND OF THE INVENTION

[0002] In cases of severe obesity, patients may currently undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the gastrointestinal tract. The procedures currently available include laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, vertical banded gastroplasty (VBG), or a more invasive surgical procedure known as a Roux-En-Y gastric bypass to effect permanent surgical reduction of the stomach's volume and subsequent bypass of the intestine.

[0003] Typically, these stomach reduction procedures are performed surgically through an open incision and staples or sutures are applied externally to the stomach or hollow body organ. Such procedures can also be performed laparoscopically, through the use of smaller incisions, or ports, through trocars and other specialized devices. In the case of laparoscopic banding, an adjustable band is placed around the proximal section of the stomach reaching from the lesser curve of the stomach around to the greater curve, thereby creating a constriction or "waist" in a vertical manner between the esophagus and the pylorus. During a VBG, a small pouch (approximately 20 cc in volume) is constructed by forming a vertical partition from the gastroesophageal junction to midway down the lesser curvature of the stomach by externally applying staples, and optionally dividing or resecting a portion of the stomach, followed by creation of a stoma at the outlet of the partition to prevent dilation of the outlet channel and restrict intake. In a Roux-En-Y gastric bypass, the stomach is surgically divided into a smaller upper pouch connected to the esophageal inflow, and

a lower portion, detached from the upper pouch but still connected to the intestinal tract for purposes of secreting digestive juices. A resected portion of the small intestine is then anastomosed using an end-to-side anastomosis to the upper pouch, thereby bypassing the majority of the intestine and reducing absorption of caloric intake and causing rapid "dumping" of highly caloric or "junk foods."

[0004] Although the outcome of these stomach reduction surgeries leads to patient weight loss because patients are physically forced to eat less due to the reduced size of their stomach, several limitations exist due to the invasiveness of the procedures, including time, use of general anesthesia, time and pain associated with the healing of the incisions, and other complications attendant to major surgery. In addition, these procedures are only available to a small segment of the obese population (morbid obesity, Body Mass Index ≥ 40) due to their complications, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

[0005] In addition to surgical procedures, certain tools exist for securing tissue such as the stapling devices used in the above-described surgical procedures and others such as in the treatment of gastroesophageal reflux disease (GERD). These devices include the GIA® device (Gastrointestinal Anastomosis device manufactured by Ethicon Endosurgery, Inc. and a similar product by USSC), and certain clamping and stapling devices as described in U.S. Pat. Nos. 5,403,326; 5,571,116; 5,676,674; 5,897,562; 6,494,888; and 6,506,196 for methods and devices for fundoplication of the stomach to the esophagus for the treatment of gastroesophageal reflux disease (GERD). In addition, certain tools, such as those described in U.S. Pat. Nos. 5,788,715 and 5,947,983, detail an endoscopic suturing device that is inserted through an endoscope and placed at the site where the esophagus and the stomach meet. Vacuum is then applied to acquire the adjacent tissue, and a series of stitches are placed to create a pleat in the sphincter to reduce the backflow of acid from the stomach up through the esophagus. These devices can also be used transorally for the endoscopic treatment of esophageal varices (dilated blood vessels within the wall of the esophagus).

[0006] There is a need for improved devices and procedures. In addition, because of the invasiveness of most of the surgeries used to treat obesity and other gastric disorders such as GERD, and the limited success of others, there remains a need for improved devices and methods for more effective, less invasive hollow organ restriction procedures.

BRIEF SUMMARY OF THE INVENTION

[0007] Devices for tissue acquisition and fixation, or gastroplasty, are described that may be utilized for creating a partition within a hollow body organ, such as the stomach, esophageal junction, and other portions of the gastrointestinal tract. Generally, the devices of the system may be advanced in a minimally invasive manner within a patient's body, e.g., transorally, endoscopically, percutaneously, etc., to create one or several divisions or plications within the hollow body organ. Such divisions or plications can form restrictive barriers within the organ, or can be placed to form a pouch, or gastric lumen, smaller than the remaining stomach volume to essentially act as the active stomach such as the pouch resulting from a surgical Roux-En-Y gastric bypass procedure. Examples of placing and/or creating divisions or plications may be seen in further detail in U.S. Pat. No. 6,558,400; U.S. Pat. App. Serial No. 10/188,547 filed July 2, 2002; and U.S. Pat. App. Serial No. 10/417,790 filed April 16, 2003, each of which is incorporated herein by reference in its entirety.

[0008] The devices may be advanced within a body through a variety of methods, e.g., transorally, transanally, endoscopically, percutaneously, etc., to create one or several divisions or plications within a hollow body organ, e.g., to create a gastric lumen or partition to reduce the effective active area of the stomach (e.g., that which receives the initial food volume), performed from within the stomach cavity. The creation of this smaller gastric lumen may be achieved in a minimally invasive procedure completely from within the stomach cavity. Moreover, the devices are configured such that once acquisition of the tissue is accomplished, manipulation of the acquired tissue is unnecessary as the devices are able to automatically configure the acquired tissue into a desired configuration.

[0009] The devices may generally comprise a first acquisition member and a second acquisition member in apposition to one another along a first longitudinal axis, wherein optionally, at least one of the acquisition members is adapted to adhere tissue thereto such that the tissue is positioned between the first and second acquisition members, and optionally wherein at least one of the acquisition members is movable relative to the first longitudinal axis between a delivery configuration and a deployment configuration. Moreover, the system may also comprise a septum,

or separator, removably positioned between the first and second acquisition members, wherein at least one of the acquisition members is movable relative to the septum between a delivery configuration and a deployment configuration.

[0010] A handle may be located at a proximal end of an elongate body or member and used to manipulate the device advanced within the hollow body organ as well as control the opening and clamping of the acquisition members onto the tissue. The elongate body may be comprised of a series of links, or of an extrusion fabricated with various lumens to accommodate the various control mechanisms of the acquisition device. Similarly, the control mechanisms may be grouped together and sheathed in a thin skin sheath, such as a heat shrink. A working lumen may extend entirely through the elongate member and may be sized to provide access to the distal end for various surgical tools, such as an endoscope or other visualization device, or therapeutic devices such as snares, excisional tools, biopsy tools, etc. once the distal end of the assembly is positioned within the hollow body organ. The acquisition members may be joined to the elongate body via a passive or active hinge member, adaptable to position the assembly. The acquisition members may generally comprise a cartridge member placed longitudinally in apposition to an anvil member. The cartridge member may contain one or several fasteners, e.g., staples, clips, etc., which may be actuated via controls located proximally on the handle assembly. Moreover, the septum or barrier may be removably positioned between the cartridge member and anvil member and used to minimize or eliminate cross acquisition of the tissue into the cartridge member and/or anvil member.

[0011] Methods of placing a partition from within a hollow body organ using the devices disclosed herein generally comprise positioning a first acquisition member and a second acquisition member adjacent to a region of tissue within the hollow body organ, wherein the first and second acquisition members are in apposition to one another along a first longitudinal axis, adhering tissue from the region to each of the first and second acquisition members, and securing the adhered tissue between the first and second acquisition members. Such a method may also involve pivoting at least one of the acquisition members about the longitudinal axis to an open or closed configuration. Another method may also comprise removing a septum from between the first acquisition member and the second acquisition member.

[0012] While the device is in a delivery configuration, i.e., where the components of the distal working portion of the device (the cartridge member and anvil member) are disposed such that the cartridge and anvil are directly positioned into apposition about the septum. Once desirably positioned, one or both of the cartridge member and anvil member may be rotated about a pivot or translationally moved in parallel to one another. Then, portions of the stomach wall may be acquired by, or drawn within their respective openings. The configuration of the cartridge member and anvil member and the positioning of the device within the stomach are such that this tissue acquisition procedure also enables the devices to be self-adjusting with respect to the acquired tissue. Moreover, the devices are configured such that portions of the stomach wall are automatically positioned for fixation upon being acquired and the tissue becomes automatically adjusted or tensioned around the perimeter of the distal working portion of the device in the stomach and within the distal working portion inner volume, to achieve the desired resulting geometry (e.g., small gastric pouch or restrictive partition or baffle). Because of the manner in which the tissue is acquired, the tissue intimately surrounds the cartridge member and anvil member to define or calibrate the subsequent volume of the resulting gastric lumen. Thus, the gastric volume may be predetermined by adjusting the volume of the cartridge member and anvil member, or the use of accessory devices such as a scope or balloon. As a result, once the desired volume is known and incorporated in the device, the user can achieve a controlled acquisition and without intraprocedural adjustments or positioning requirements.

[0013] The septum may act effectively as a barrier between the openings to facilitate the acquisition of the tissue to their respective openings while minimizing or eliminating cross acquisition of the tissue into the cartridge member and/or anvil member. In other alternatives, the septum may be omitted from the device and acquisition of the tissue may be accomplished by sequentially activating vacuum forces within the openings. Once the tissue has been acquired, the septum may be removed from between the cartridge member and anvil member by translating the septum distally or proximally of the cartridge member and anvil member or left within the stomach for later removal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figs. 1A and 1B show side and detailed side views, respectively, of one variation of an exemplary gastroplasty device described herein.

[0015] Figs. 2A and 2B show perspective detailed views of an exemplary gastroplasty device described herein.

[0016] Figs. 3A and 3B show perspective and end views, respectively, of a cross-sectioned portion of an exemplary gastroplasty device.

[0017] Figs. 4A and 4B show representative illustrations of how a gastroplasty device may be advanced transorally through the esophagus of a patient and positioned within the stomach cavity of a stomach.

[0018] Figs. 5A to 5D show end views of an example of how an exemplary gastroplasty device may be used to acquire and fasten tissue within a hollow body organ.

[0019] Fig. 5E illustrates a resulting fastened gastric lumen that may be formed using the gastroplasty devices described herein.

[0020] Figs. 5F and 5G demonstrate how a distal working portion of a gastroplasty device, and an inner volume, respectively, help to define the final configuration of the acquired tissue.

[0021] Figs. 5H and 5I show perspective and cross sectional views of illustrative tissue configurations that may be formed with the gastroplasty devices and methods described herein.

[0022] Figs. 6A and 6B show perspective and end views, respectively, of one variation of a gastroplasty device, wherein the septum is in position.

[0023] Figs. 7A and 7B show perspective and end views, respectively, of the device of Fig. 6A in an open configuration.

[0024] Figs. 8A and 8B show perspective and end views, respectively, of the device of Fig. 6A in an open configuration with the septum removed.

[0025] Figs. 9A and 9B show perspective and end views, respectively, of the device of Fig. 6A in a closed configuration.

[0026] Figs. 10A to 10C show end views of the cartridge member and anvil member during delivery, during tissue acquisition, and prior to clamping of the tissue, respectively, in one example of how a clamping cable may be routed with respect to an optional septum.

[0027] Figs. 11A and 11B show perspective and end views, respectively, of another variation of a suitable gastroplasty device.

[0028] Figs. 11C and 11D show perspective views of a gastroplasty device with and without a septum, respectively.

[0029] Figs. 12A to 12C show perspective views of yet another variation of a gastroplasty device.

[0030] Figs. 13A and 13B show cross-sectioned perspective and end views, respectively, of alternative acquisition pod assembly.

[0031] Figs. 13C and 13D show cross-sectioned perspective and end views, respectively, of the device of Figs. 13A and 13B under a high vacuum pressure.

[0032] Figs. 14A to 14D show perspective views of the operation of another variation of a gastroplasty device utilizing parallel pod motion.

[0033] Fig. 14E shows a cross-sectional perspective view of a portion of the pod members in an open configuration with a septum still in place between the cartridge member and anvil member.

[0034] Fig. 15 shows a perspective view of yet another variation of a gastroplasty device utilizing a translational trolley plate.

[0035] Figs. 16A to 16D show side, end, bottom, and perspective views, respectively, of a variation of a gastroplasty device, which utilizes a static acquisition pod.

[0036] Fig. 16E shows a bottom view of one variation of a gastroplasty device having an arcuate configuration.

[0037] Fig. 17 shows a perspective view of a device having an optional feature of projections or serrations which may be defined along the mating surfaces of the cartridge member and/or anvil member.

[0038] Figs. 18A and 18B show perspective and cross-sectional end views, respectively, of another optional feature of one or more rotatable shafts which may be integrated into the device.

[0039] Figs. 19A and 19B show perspective and detailed perspective views, respectively, of a device having a curved or adjustable segmented staple cartridge.

[0040] Figs. 20A and 20B show perspective views of a septum assembly having a tapered edge for facilitating removal of the septum from the hollow body organ.

[0041] Figs. 21A and 21B show perspective views of an alternative septum assembly having ribbed surfaces.

[0042] Fig. 21C shows a side view of one example of how collapse of the septum may be facilitated by withdrawing the septum into a receiving member.

[0043] Figs. 22A and 22B show perspective and end views, respectively, of a septum variation having at least two transverse septum members extending to opposite sides of the longitudinal septum member.

[0044] Fig. 23A illustrates an end view of an extendable septum assembly positioned between pod members and placed against stomach tissue.

[0045] Figs. 23B and 23C show side views of variations for extending the septum assembly from a low profile delivery to an extended deployed configuration.

[0046] Figs. 24A and 24B show end views of an alternative septum assembly which may be configured to deploy an extendable septum from a rolled-up configuration.

[0047] Figs. 25A and 25B show perspective views of an alternative septum assembly having a collapsible septum member.

[0048] Figs. 25C and 25D show end views of the septum of Fig. 25A in an expanded or extended configuration and in a collapsed configuration.

[0049] Figs. 26A to 26C show end, bottom, and perspective views, respectively, of yet another alternative septum having radiused corners.

[0050] Figs. 27A and 27B show perspective views of an alternative septum assembly having a low profile delivery configuration where the septum may be comprised of two elongate T-shaped members.

[0051] Figs. 28A to 28C show perspective views of an example of a clamping mechanism having two cam members.

[0052] Fig. 29A shows a perspective view of one example of how clamping cables may be routed through a gastroplasty device described herein.

[0053] Fig. 29B shows a cross-sectioned end view of a parallel clamping device with the septum shown.

[0054] Figs. 30A and 30B show side and edge views of an alternative gastroplasty device, utilizing linked pod members.

DETAILED DESCRIPTION OF THE INVENTION

[0055] Gastroplasty devices for tissue acquisition and fixation, and methods of using them are described. In general, the gastroplasty devices described herein may be utilized for creating a partition within a hollow body organ, such as the stomach, esophageal junction, and/or other portions of the gastrointestinal tract. The gastroplasty devices may be advanced within a body

through a variety of methods, e.g., transorally, transanally, endoscopically, percutaneously, etc., to create one or several divisions or plications within the hollow body organ, e.g., to create a gastric lumen within the stomach. Further, the gastroplasty devices may be assisted through the use of laparoscopic guidance, in particular, visualization of the external surface of the hollow body organ to assist in placement of the device, or within the organ cavity to monitor the procedure. Similarly, the devices of the present invention may be used in conjunction with other laparoscopic procedures, or may further be modified by an additional step or procedure to enhance the geometry of the partition. For example, upon placement of a partition of the present invention, it may be desirable to perform a secondary step either transorally, or laparoscopically, to achieve the desired gastroplasty geometry, such as the placement of a single fold or plication within the gastric lumen or pouch as described in U.S. Pat. App. Serial No. 10/188,547, which was filed 7/2/2002 and is incorporated by reference herein in its entirety, to further restrict the movement of food through the pouch, or the laparoscopic placement of a band, clip, ring or other hollow reinforcement member at the outlet of the gastric lumen such as is done in a VBG, or lap-band procedure to reinforce or narrow the outlet of the lumen.

[0056] The gastroplasty devices described here, allow for the creation of a smaller gastric lumen to be achieved in a minimally invasive surgical procedure completely from within the stomach cavity. Moreover, the devices described herein are configured such that once acquisition of the tissue is accomplished, any manipulation of the acquired tissue is unnecessary as the devices are able to automatically configure the acquired tissue into a desired configuration whereby the geometry of the devices regulates or prescribes the resulting tissue geometry at the time of acquisition. In operation, the perimeter of the device, and any openings therein, form the template or mold cavity around and into which tissue flows, thereby creating a tissue structure that reflects the geometry of the mold. That is, as the devices are configured such that portions of the stomach wall are automatically positioned for fixation upon being acquired, and the tissue becomes automatically adjusted or tensioned around the perimeter of the distal working portion of the device in the stomach and within the distal working portion inner volume, to achieve the desired resulting geometry (e.g., small gastric pouch or restrictive partition or baffle). Because of the manner in which the tissue is acquired, the tissue intimately surrounds the cartridge member and anvil member

to define or calibrate the subsequent volume of the resulting gastric lumen. Thus, the gastric volume may be predetermined by adjusting the volume of the cartridge member and anvil member. As a result, once the desired volume is known and incorporated in the device, the user can achieve a controlled acquisition and without intraprocedural adjustments or positioning requirements. Subsequent manipulation of the tissue may be performed, if desired, to effect certain configurations; however, this manipulation may be omitted entirely.

[0057] Turning to the figures, Fig. 1A shows a side view of one variation of gastroplasty assembly **10**. Assembly **10** may be generally comprised of an elongate tubular member **12** having handle assembly **16** connected at a proximal end **14**. An integrated access assembly **18** may also be connected at proximal end **14** for providing access to working lumen **22** defined within elongate member **12**. Elongate member **12** may have a circular or elliptical cross-sectional area. Alternatively, the cross-sectional area may take on any number of different cross-sectional configurations, e.g., hexagonal, octagonal, etc., provided that it presents an atraumatic surface to the tissue surfaces within the body. In addition, elongate member **12** may be curved, or may comprise a series of links as described in U.S. Pat. App. Serial No. 10/686,326, which was filed on 10/14/2003, and is incorporated by reference in its entirety herein. In this way, a curved or flexible elongate member, or an elongate member comprising a series of links will help to increase the flexibility of the elongate member, and hence increase the ease in which the device is handled and operated. Working lumen **22** may extend entirely through tubular member **12** and may be sized to provide access to distal end **20** for various surgical tools or therapies once distal end **20** of assembly **10** is positioned within a hollow body organ, and in particular may be useful to place an endoscope or other visualization tool. Alternatively, a fiberscope or other type of visualization tool may be integrated within the elongate member. Examples of useful scopes may be the Olympus GIF P140, the Fujinon EG 25PE, and the like. Gastroplasty device **24** is typically positioned at the distal end of tubular member **12** and is also generally configured to be advanced atraumatically through the body of a patient and within a hollow body organ, e.g., esophagus, stomach, etc. Alternatively, an optional separate thin walled oversheath, may also be placed over the acquisition device, including the elongate member, to assist in placement, or may be placed over a guidewire or obturator down the esophagus prior to placement of the gastroplasty device and removed with the gastroplasty

device once the procedure is complete. The liner may be made of a thin wall polymer such as polyolefin, polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), silicone and the like, having a wall thickness between 0.004" and 0.025". This liner can serve to guide the gastroplasty device, as well as help to limit trauma to the esophagus and other delicate structures.

[0058] Fig. 1B shows a closer detail view of the gastroplasty assembly **10**. As shown there, the device comprises a distal working portion, which comprises a cartridge member or pod **26** placed longitudinally in apposition to anvil member or pod **28**. As described above, when the device is in use, the tissue of the stomach wall (including, in some instances, the muscular tissue layers) are adjusted or tensioned around the perimeter of the distal working portion, and within the distal working portion inner volume, to achieve a desired resulting geometry (e.g., small gastric pouch or restrictive partition or baffle). Thus, the gastric volume may be predetermined by adjusting the volume of the distal working portion, inner or outer profile. Cartridge member **26** may contain one or several fasteners, e.g., staples, clips, etc., which may be actuated via controls located proximally on handle assembly **16**. A septum or barrier **32**, described in further detail below, may be removably positioned between cartridge member **26** and anvil member **28** while connection member **30** may connect device **24** to tubular member **12**.

[0059] Handle assembly **16** may be variously configured depending upon the desired functionality to be implemented on assembly **10**. In this variation, handle assembly **16** may generally comprise handle **34** for use by the surgeon or physician in advancing, withdrawing, or articulating assembly **10**. A control for articulating the device **24** between an open and closed configuration may be located on handle **34**, shown as clamping control knob **36**, while a separate control mechanism, shown here as fastener firing lever **38**, may be utilized for deploying the fasteners located within cartridge member **28**. Although specific types of controls are shown, these are intended only to be illustrative of the types of control mechanisms which may be utilized and are not intended to be limiting in scope.

[0060] Assembly **10** may further have one or several integrated vacuum ports **40** proximally located on elongate member **12** for fluid connection to one or several vacuum pumps (not shown). One or each of cartridge **26** or anvil **28** members may be fluidly connected through a common tube

or channel or through individually corresponding tubes or channels through elongate member **12** to vacuum ports **40**. Additionally, a scope seal housing **42** configured to provide access to the working lumen **22** may also be optionally provided near or at the proximal end of elongate member **12** for the insertion of various tools and devices through elongate member **12** for accessing the distal end of the assembly **10**. An optional auxiliary port **44** may also be provided for allowing fluid communication via a channel or tubing through elongate member **12** between the proximal and distal ends of the assembly **10**. Auxiliary port **44** may be utilized for various purposes, e.g., delivery of fluids or gases into the hollow body organ for transporting drugs or providing insufflation, etc. As noted above, the elongate body may be comprised of a series of links, similar to those described in U.S. Pat. App. Serial No. 10/686,326, or of an extrusion fabricated with various lumens to accommodate the various control wire and mechanisms of the acquisition device. Similarly, the control mechanisms may be grouped together with a flexible band, and then sheathed in a thin skin sheath, such as heat shrink. The elongate member may also be a combination of an extrusion and a thin wall sheath to allow for flexibility, and may utilize braided materials, e.g., stainless steel or superelastic materials such as Nickel-Titanium alloy, integrated in the wall of the sheath to prevent kinking and enhance torqueability.

[0061] A detailed view of one variation of the gastroplasty devices described herein is shown in the perspective view of Fig. 2A. The cartridge member **26** and anvil member **28**, as described above, may extend longitudinally from the distal end of elongate member **12** via connection member **30**. The cartridge member **26** and anvil member **28** may be both or singularly articulatable relative to one another or relative to elongate member **12**. A pivot **50** longitudinally positioned between cartridge member **26** and anvil member **28** may be configured to enable the device to be pivoted into an open configuration for the acquisition of tissue and a closed or deployment configuration for delivery or advancement of the device into the hollow body organ.

[0062] If both members **26, 28** are articulatable, they may be configured to be either simultaneously or sequentially articulatable. The cartridge member **26** may contain a cartridge **52** container fasteners along an outer edge of the member **26** while the anvil member **28** may have an anvil positioned along an outer edge of the member **26** such that the anvil corresponds to the number and position of fasteners within cartridge **52**. One or both members **26, 28** may also define openings

56, 58, respectively, along a portion of the length or the entire length of each of the members 26, 28. One or both of these openings 56, 58 may be connected via tubing through vacuum lumens 60, 62, respectively, defined through elongate member 12 to the vacuum ports 40 located at the proximal end of member 12. Alternatively, a central vacuum lumen may supply both ports, or may bifurcate at the proximal or distal end of member 12. Elongate member 12 may also define various cable lumens 64, 66 for the passage of cables for controlling the opening and closing of members 26, 28 as well as additional cable lumen 68 for the passage of cables for actuating deployment of the fasteners from within cartridge 52. Moreover, cable lumen 70 may be used for the passage of cables used for controlling the clamping of the members 26, 28 towards one another.

[0063] Each of the members 26, 28 may have openings 72, 74 and 76, 78, respectively, defined at the outer corners of each member opposite pivot 50 to allow for the routing and passage of clamping cables through the device for enabling cartridge member 26 and anvil member 28 to be clamped closed towards one another. Fig. 2B shows a perspective view of the acquisition and fixation device of Fig. 2A with the vacuum tubing and cables routed through the device. As shown, vacuum tubing 80, 82 may be routed through elongate member 12 into a proximal end of one or each of cartridge member 26 and/or anvil member 28 for fluid connection with respective openings 56, 58. Cables 84, 86 may be utilized for opening and closing the cartridge member 26 and anvil member 28 and cable 88, which may be routed into cartridge member 26, may be positioned and utilized, e.g., for pulling or pushing a wedge mechanism, to deploy fasteners out of cartridge 52. Moreover, clamping cables 90 may be passed through elongate member 12 and routed through cartridge member 26 and anvil member 28 such that cables 92, 94 are passed through openings 72, 74 and 76, 78 for clamping cartridge member 26 and anvil member 28 closed. Cables 84 and 86 may be replaced by torque shafts connected to handles at the proximal end of the device, to open and close the cartridge and anvil members.

[0064] Figs. 3A and 3B show perspective and end views, respectively, of a cross-sectioned portion 100 of a suitable gastroplasty device. As may be seen, septum 32 may be positioned to extend from pivot 50 effectively separating vacuum openings 56, 58 within cartridge member 26 and anvil member 28, respectively. Adjacent to opening 56 is fastener cartridge 52 and adjacent to opening 58 is anvil 54 positioned such that when septum 32 is removed or displaced, the articulation

of cartridge member **26** and anvil member **28** towards one another about pivot **50** positions cartridge **52** in apposition to anvil **54**. Alternatively, anvil member **28** cartridge member **26** may be non-movable or in a fixed position relative to the longitudinal axis of the device. In this configuration, fastener cartridge **52** and optionally anvil **54**, may be actuated to eject from their respective housings to fasten the acquired tissue.

[0065] Figs. 4A and 4B show representative illustrations of how gastroplasty device **24** may be advanced transorally through the esophagus **ES** of a patient and positioned within stomach cavity **SC** of stomach **110**. Making reference now to Fig. 4A, device **24** may be articulated outside the patient via handle **16** so that the proximal portion of elongate member **12** may be positioned such that the spine of the device is placed against a portion of lesser curvature **LC** and opposite greater curvature **GC**. In this way, the device **24** extends between the gastroesophageal junction **GEJ** towards pylorus **PY**. In addition Fg. 4A depicts the use of a flexible endoscope **EN** alongside the device **10** to allow direct visualization of the procedure, including the fixation step whereby the scope can then be removed, leaving additional volume remaining in the smaller gastric pouch that may be helpful when removing or detaching the gastroplasty device **24** from the acquired tissue once it has been fixed. If no direct visualization is required, but additional removal volume is desired, an optional expandable balloon, or other expandable member **EM** may be used alongside the spine of the gastroplasty device, or may be integrated into the spine of the gastroplasty device using known techniques. Fig. 4B shows the positioning of gastroplasty device **10** without the aid of an endoscope, or other direct visualization technique.

[0066] Fig. 5A shows an end view of device **24** positioned within stomach cavity **SC** with pivot **50** placed against stomach wall **120**, for instance, against lesser curvature **LC** in one example of how the device **10** may be used to effect the creation of a gastric lumen or partition within stomach cavity **SC**. The device is advanced through the esophagus **ES** while in a deployment configuration, i.e., where the distal working portion of the device **DWP** is configured so that cartridge member **26** and anvil member **28** are closed such that openings **56**, **58** and cartridge **52** and anvil **54** are directly positioned in apposition about septum **32**. When desirably positioned, one or both of cartridge member **26** and anvil member **28** may be rotated about pivot **50** in the direction of the arrows shown. Fig. 5B shows cartridge member **26** and anvil member **28** rotated at an angle

with a vacuum force activated within openings **56, 58**. In certain embodiments where no pivoting or movement of the cartridge member **26** or anvil member **28** is necessary, the device is advanced in a static state. As seen, portions of the stomach wall **120** may be acquired and drawn within respective openings **56, 58**. The configuration of cartridge member **26** and anvil member **28** and the positioning of the device **24** within stomach cavity **SC** are such that this tissue acquisition procedure also enables the device **24** to be self-adjusting with respect to the acquired tissue **122, 124**. More particularly, the device **24** is configured such that portions of the stomach wall **120** are automatically positioned for fixation upon being acquired and the device **24** becomes automatically adjusted within stomach cavity **SC** relative to the stomach wall **120**. Furthermore, because of the manner in which the tissue is acquired, the tissue intimately surrounds the cartridge member **26** and anvil member **28**, i.e., the distal working portion of the device **DWP**, by being tensioned or held around the perimeter **PT** of the distal working portion of the device and within the inner volume **IV** of the distal working portion of the device to define the subsequent volume or resulting geometry **RG** resulting gastric lumen as shown by the diagonal and hatched lines respectively in Figs. 5F and 5G. An illustrative depiction of a cross section of a resulting tissue geometry is provided in Fig. 5E. Other depictions of resulting tissue geometries are provided in Figs. 5H and 5I. Shown there are front views of the distal working portion of the device, and cross sectional views (along lines A-A and B-B respectively) of the resulting tissue geometries. In Fig. 5H, the distal working portion has been configured to provide one plication **P**, whereas in Fig. 5I, the distal working portion has been configured to provide more than one plication. Multiple plications may be useful, for example, to help increase the ease in which the distal working portion of the device is removed from a patient after tissue has been acquired and fixed. Thus, as these Figs. illustrate, the gastric volume may be predetermined by adjusting the volume of the cartridge member **26** and anvil member **28**, or geometry of the distal working portion of the device, e.g., the distal working portion of the device may be configured so that the gastric tissue has results in the geometries described, for example, in U.S. Pat. App. Serial No.10/417,790, which was filed on April 16, 2003 and is hereby incorporated by reference in its entirety.

[0067] Optional septum **32** may act effectively as a barrier between openings **56, 58** to facilitate the acquisition of the tissue **122, 124** into their respective openings **56, 58** while

minimizing or eliminating cross acquisition of the tissue into cartridge member **26** and/or anvil member **28**. In another alternative, septum **32** may be omitted from the device **24** and acquisition of the tissue may be accomplished by sequentially activating vacuum forces within openings **56** and **58**. That is, the cartridge and anvil members may be orient towards the tissue surface in a sequential fashion, acquiring the tissue adjacent thereto. However, when a septum is employed, it may be removed from between cartridge member **26** and anvil member **28** by translating the septum **32** distally, laterally, or proximally of cartridge member **26** and anvil member **28**, after the tissue has been acquired. Alternatively, the septum may be left within stomach cavity **SC** for later removal, or as will be described in more detail below, may be left within the stomach cavity to biodegrade. Fig. 5C shows septum **32** having been removed so that cartridge member **26** and anvil member **28** may be pivoted from the open configuration back to its closed configuration in the direction of the arrows shown. Because the septum **32** has been removed, tissue region **126** may now be presented for clamping between cartridge **52** and anvil **54**.

[0068] As shown in Fig. 5D, cartridge member **26** and anvil member **28** may be simply clamped over tissue region **126** and fastened by deploying one or several fasteners from within cartridge **52**. In acquiring the tissue **122**, **124**, manipulation of the tissue region **126** or the acquired tissue **122**, **124** may be eliminated entirely due to the automatic positioning of the tissue for fastening. Once the clamped tissue has been fastened, the device **24** may be withdrawn entirely from the stomach cavity **SC**, as shown in Fig. 5E. As seen, one or several fasteners **128**, e.g., a line of staples, may hold the tissue in its fastened configuration to result in the creation of a partition, creating a restriction, or when desired, creating a gastric lumen or pouch **130**, separate from the remainder of the stomach cavity.

[0069] Alternative variations of gastroplasty device **24** may also be utilized. For instance, Fig. 6A shows a perspective view of another variation in device **140** partly cross-sectioned for the sake of clarity. In this variation, cartridge member **142** and anvil member **144** may define a curved or arcuate shape. The septum may also be configured to have a longitudinal barrier portion **146** with a first transverse barrier **152** and a second optional transverse barrier **154**. One or both barriers **152**, **154** may extend in a curved or arcuate shape from the longitudinal septum **146** such that an atraumatic surface is presented to tissue during advancement within the patient. The septum may be

retained between cartridge member **142** and anvil member **144** via septum detent **148** being slidably positioned within septum retaining channel **150**, which extends longitudinally between cartridge member **142** and anvil member **144**. Longitudinal septum **146** may partition openings **156**, **158**, which may function in the same manner as described above for adhering tissue. It may be advantageous to house a pressure transducer **159** near or within the pod(s) or opening(s), to allow the device user to accurately gauge measurement of pressure at the site of tissue adhesion. A drop of pressure within the pod or opening signals to the user that the vacuum seal has been compromised, and therefore the amount of tissue adhered to the system is not optimal. Readings from the transducer can serve as feedback to the user that sufficient vacuum pressure has been maintained, and therefore be a "go-nogo" trigger to the user. Fig. 6B shows a cross-sectional end view of the variation **140** from Fig. 6A. As illustrated, cartridge **162** may retain one or several fasteners **166**, shown in this variation as staples, in corresponding apposition to anvil **164** when cartridge member **142** and anvil member **144** are in the closed or delivery configuration. It should be noted that while a rectangular staple jaw is depicted, it may be desirable to provide a curved track or wedge to facilitate the placement of a curved line of staples, from the rectangular jaw. Pivoting member or plate **168**, which may function to facilitate the pivoting the device, may be seen as placed over the outer surface of cartridge member **142** and anvil member **144**.

[0070] Fig. 7A shows a perspective view of an open configuration **170** of the device of Figs. 6A and 6B for receiving tissue within openings **156**, **158**. Septum **146** may be removed from the device by translating the septum **146** longitudinally in the direction of the arrow. As shown in the end view in Fig. 7B, pivoting region **160** may be seen expanded via pivoting plate **168**, which may be made from various biocompatible materials, e.g., stainless steel, polymers, etc., and which is sufficiently flexible to enable the device to transition between the open and closed configurations. Fig. 8A shows the open configuration **180** in which the septum **146** has been removed from the device. As described above, the septum may be removed once the tissue has been acquired within their respective openings. Fig. 8B shows an end view of the device with the septum removed. The tissue acquired within open region **182** may be clamped by articulating cartridge member **142** and anvil member **144** in the direction of the arrows to result in the configuration shown in Fig. 9A, which shows the device **190** ready for fastening the clamped tissue within clamping region **192**.

Fig. 9B shows an end view of the device configured into its closed configuration for fastening the tissue within clamping region **192**. As described above, because the stomach tissue may be automatically configured for fastening once the tissue has been acquired, manipulation of the tissue is rendered unnecessary during clamping and fastening of the tissue.

[0071] In facilitating the clamping of cartridge member **142** and anvil member **144** onto the tissue, clamping cables may be utilized, as described above. Figs. 10A to 10C show end views of cartridge member **142** and anvil member **144** during delivery, during tissue acquisition, and prior to clamping of the tissue, respectively, and one example of how clamping cable **200** may be routed with respect to septum **146**. Fig. 10A shows septum **146** in position between cartridge member **142** and anvil member **144** with clamping cable **200** routed within a cable constraining slot **202** defined in an adjacent portion of septum **146**. The clamping cable **200** may extend between cartridge member **142** and anvil member **144** through clamping cable openings **204** defined in both cartridge member **142** and anvil member **144**. Once the septum **146** is removed, as shown in Fig. 10C, the clamping cable **200** may be released from slot **202** and tensioned to bring cartridge member **142** and anvil member **144** towards one another, as described in further detail below. Other mechanisms of clamping are also suitable, for example, the tissue may be clamped using hydraulic, pneumatic, or electropneumatic mechanisms, all of which are well known in the art.

[0072] Figs. 11A and 11B shows perspective and end view of another alternative gastroplasty device **210**. This variation shows cartridge member **212** and anvil member **214** in a closed configuration with extension member **218** connected to longitudinal pivot **216**. The septum, in this variation, may comprise a longitudinal septum member **220** and a perpendicularly positioned transverse septum member **222**, which may extend partially over the openings **228, 230** when cartridge member **212** and anvil member **214** are in an open configuration, as shown in Fig. 11C. Respective vacuum tubing **224, 226** may be fluidly connected to one or both openings **228, 230** defined within their respective members **212, 214**. Fig. 11D illustrates the device with the septum translated distally showing a clearer view of opening **230**.

[0073] Figs. 12A to 12C show perspective views of yet another variation of gastroplasty device **240**. In this variation, cartridge member **242** and anvil member **244** may be pivotally

connected via longitudinally defined pivot **246**. Similar to the variation of Figs. 11A and 11B, the septum may also comprise a longitudinal septum member **248** positionable between members **242**, **244** and an optional perpendicularly configured transverse septum member **250**. Also seen are vacuum tubing **252**, **254** fluidly coupled to their respective openings **260**, **262**. As discussed above, because the resulting gastric lumen may be defined by the shape and volume of the device, cartridge member **242** and anvil member **244** may each define tapered distal ends **256**, **258**, respectively, to provide an atraumatic surface for advancement within the patient and to facilitate formation of a gastric lumen having a tapered distal region. The proximal shoulder of the members may also be tapered to facilitate removal of the device once the procedure has been completed. Moreover, this variation also shows openings **260**, **262** which may be elongated to extend over a majority of the length of their respective members **244**, **242**.

[0074] Yet another variation of an alternative acquisition pod assembly **270** is shown in the cross-sectioned perspective view of Fig. 13A. This variation may generally comprise pod walls **272**, **274** each defining an undercut section **276**, **278** having projections or serrations **280**, **282** along their edges directed or angled towards one another. The assembly **270** may be comprised of a biocompatible material, e.g., polymers, polycarbonates, etc., which has an elastic bending modulus sufficiently low to allow for plastic deformation of the pod assembly **270** to occur. A barrier **286** having a plurality of openings **288** defined over its surface may be positioned between pod walls **272**, **274** such that tissue acquisition chamber **284** is defined as shown. A vacuum chamber **290** may be located beneath barrier **286** with vacuum plenum **292** defined by chamber **290** and barrier **286**.

[0075] In operation, as shown in Fig. 13B, tissue **294** may be acquired against or within acquisition chamber **284** by the application of a relatively low pressure vacuum force applied through plenum **292**, which may create a low vacuum within chamber **284** through openings **288**. Once the tissue **294** has been first acquired, a higher pressure vacuum force may be applied through plenum **292** such that pod walls **272**, **274** and undercut sections **276**, **278**, respectively, are plastically deformed and drawn towards one another in the direction of the arrows, as shown in Fig. 13C. As the undercut sections **276**, **278** are drawn inwards and shown in Fig. 13D, the acquired tissue **294** may become pinched at retained tissue region **296** resulting in a temporary mechanical fixation of the tissue. A cessation of the high vacuum force may then result in a relaxation of the

pod walls **272, 274** and ultimately of the release of the acquired tissue **294** when the vacuum force is ceased altogether. Spearing mechanisms or a plurality of sharp hooks may also be used, in conjunction with, or in lieu of, the undercut sections described above.

[0076] Yet another variation of a gastroplasty device **300** is shown in the perspective views of Figs. 14A to 14D. This particular variation may utilize a parallel translational motion in moving the cartridge member **306** and anvil member **308** between the open and closed configuration rather than a pivoting motion, as described above in other variations. As shown in Fig. 14A, device **300** may comprise pod assembly **302** connected at the distal end of elongate tubular member **304**. Septum **310** may be removably positioned between cartridge member **306** and anvil member **308**. A groove plate **312** defining a longitudinally extending slot may be positioned adjacent to cartridge member **306** and anvil member **308** on a side opposite to that of septum **310**.

[0077] Fig. 14B shows cartridge member **306** and anvil member **308** articulated away from one another into an open configuration while maintaining a parallel orientation relative to one another. In this open configuration, tissue may be acquired and drawn into respective pod members **302** on opposite sides of septum **310**. Groove plate **312**, which may be comprised of various biocompatible materials, e.g., stainless steel, polycarbonate, various polymers, etc., may be held stationary relative to pod assembly **302** and may further help maintain cartridge member **306** and anvil member **308** in their parallel orientation during reconfiguration. Fig. 14C shows septum **310** removed from between cartridge member **306** and anvil member **308** by being translated distally via septum control member **314**, which may be articulated from a proximal end of elongate member **304**. Once the septum **310** has been removed, cartridge member **306** and anvil member **308** may be articulated to clamp onto the tissue while maintaining their parallel configuration, as shown in Fig. 14D. Once the tissue has been clamped, cartridge member **306** may be actuated to fasten the tissue. Fig. 14E shows a cross-sectional perspective view of a portion of pod members **302** in an open configuration with septum **310** still in place between cartridge member **306** and anvil member **308**. As shown, cartridge member **306** and anvil member **308** along with acquisition chambers **316, 318**, respectively, may be seen maintaining a parallel configuration relative to one another.

[0078] Fig. 15 shows a perspective view of yet another variation of a gastroplasty device **320** positioned upon the distal end of elongate tubular member **336**. Similar to the device of Fig. 14A, cartridge member **322** and anvil member **324** may be configured to open and close while maintaining a parallel configuration relative to one another. Optional septum **326** may also be positionable between members **322, 324**. However, device **320** may comprise a translationally movable trolley plate **328** which may be advanced or retracted longitudinally. At least two wedging members **330, 332** may protrude from plate **328** at an angle which correspondingly abuts with the distal ends of members **322, 324** such that when plate **328** is longitudinally translated, wedging members **330, 332** may drive cartridge member **322** and anvil member **324** towards one another in a parallel configuration to clamp onto any tissue which may have been acquired by device **320**. A septum groove **334** may be defined longitudinally along the plate **328** so as to enable unhindered movement relative to the septum **326**. Cartridge member **322** and anvil member **324** may also be configured such that when trolley plate **328** compresses the members **322, 324** onto tissue, fasteners are automatically deployed into the tissue to fasten it.

[0079] Figs. 16A to 16C show side, end, and bottom views, respectively, of another variation of gastroplasty device **340**. Generally, while other variations have enabled movement of respective pod members, this variation may maintain a static acquisition pod. Vacuum pod **342** may be comprised of a variety of biocompatible materials, e.g., polycarbonate, etc., shaped into opposing walls having vacuum plenums **348, 350** defined along the lengths of the opposing walls. While two vacuum plenums are depicted, it should be understood that any number of vacuum plenums may be employed as well. For example, a single vacuum plenum may be used. Similarly, three or more vacuum plenums may be used. A septum having a longitudinal member **346** and an optional perpendicularly positioned transverse member **344** may be positioned to fit within vacuum pod **342** such that at least two tissue acquisition chambers **352, 354** are formed along the length of pod **342**. Alternatively, the septum may only include longitudinal member **346**, and may omit any transverse members entirely, which may aid in reducing the overall profile of the distal working end of the device. The septum may generally be comprised of a similar material as vacuum pod **342** and may be further coated with a layer of a lubricious material, such as Teflon®. Furthermore, the septum may be formed of a bioabsorbable material that may either dissolve upon exposure to gastric fluids

after tissue has been acquired, or may be releaseably attached to pods or chambers and fixed in place between tissue folds (e.g. left behind) once device is removed. The septum may also have end member **356** at one end of the septum which may act as a stop for the device **340**. Fig. 16D shows a perspective view of acquisition device **340** revealing the vacuum plenum defined along the bottom of pod **342**. While rectangular devices are depicted in Figs. 16 A-16D, it should be understood that the device **343** can have a curved or arcuate shape as well, as shown in Fig. 16E. Also depicted there are optional septum **345** and a single vacuum plenums **347**.

[0080] To facilitate the acquisition of the tissue, various features may be incorporated into any of the variations described herein. For instance, one optional feature may be seen in Fig. 17, which shows a perspective view of gastroplasty device **360** having a plurality of projections or serrations **366, 368** defined along the mating surfaces of cartridge member **362** and/or anvil member **364**. Serrations **366, 368** may be positioned adjacent to the cartridge and/or anvil to provide additional mechanical support of the tissue positioned between clamped members of the acquisition device **360** during tissue fixation. Alternatively clearance cuts (not shown) on the cartridge may be included to reduce the surface area and required clamping force for fixation, as well as adding traction to the system. As described above, spearing mechanisms, or sharp projections may be used as well.

[0081] Another optional feature which may be integrated with the devices herein is shown in the perspective view of gastroplasty device **370** of Fig. 18A. A single pod member **372** is shown for illustrative purposes as the feature of a rotatable shaft may be integrated into any of the devices described herein. Pod member **372** may define a opening **374** along its length for receiving tissue therein, as described above; however, the device may also comprise at least one rotatable shaft **376** positioned longitudinally within the pod member **372** adjacent to the opening **374**. The rotatable shaft **376** may define one or several projections or serrations **378** along its surface such that tissue drawn into the opening **376** via a vacuum force may also be mechanically acquired by rotation of the shaft **376** in a first direction to allow serrations **378** to become affixed to the tissue. The shaft **376** may be rotated in a second opposite direction to release the acquired tissue. Moreover, the pod member **372** may acquire the tissue with the vacuum force alone, as described above, with the rotatable shaft **376** alone, or with a combination of both the vacuum force and shaft **376** operated in

conjunction with one another. Fig. 18B shows a cross-section of pod member **372** having a second rotatable shaft **380** also defining projections or serrations **382** along its surface. In the case of two shafts utilized together, they may be configured to be counter-rotating such that the acquired tissue **384** is optimally retained within opening **374**. Likewise, to release the acquired tissue **384**, the shafts **376, 380** may be counter-rotated in the opposite direction.

[0082] Yet another feature which may be integrated with the devices herein is shown in the perspective view of Fig. 19A, which illustrates acquisition and fixation device **390** having a single pod member for the sake of clarity. Also shown are septum **400** and opening **402**. A segmented staple cartridge **392** having an adjustable curvature and height may be integrated into any number of the devices described above. Cartridge **392** may be comprised of one or more staple cartridge segments **394** which are pivotally connected to one another via joints **396** which may allow not only pivotal side-to-side motion between segments **394** but also height adjustments relative to one another.

[0083] Each staple cartridge segment **394**, as seen in the detail perspective view of Fig. 19B, may each define staple openings **398**. In connecting with adjacent cartridge segments **394**, a radiused pivot member **404** may extend from one side of the segment **394** and a receiving cavity **406** may be defined in the opposite side of the segment **394**. Each pivot member **404** may extend away from segment **394** such that when positioned into a corresponding receiving cavity **406**, adequate spacing exists between segments **394** such that side-to-side motion is possible between the segments **394** to define a curvature of the resulting cartridge **392**. Moreover, because of the translational fit between pivot member **404** and cavity **406**, the heights of different segments **394** may be varied to define a curve in the height of cartridge **392**, as shown by height differential **Z** in Fig. 19A and the height differences between adjacent segments **394** in Fig. 19B. Accordingly, cartridge **392** may be varied in length by varying the number of segments utilized, as well as varied in curvature and in height. The corresponding anvil member may be adjusted to accordingly match the curvature of the cartridge **392**.

[0084] In addition to variations on types of pod members and tissue acquisition enhancements, the septum may also be adjusted in various ways to accommodate different devices

and desired results. For instance, gastroplasty device **410** may be seen in the perspective view of Fig. 20A with one variation of septum assembly **412** positioned between pod members **422, 424**. Septum assembly **412** may be seen in better detail in the perspective view of Fig. 20B. In this variation, the septum may have a transverse septum member **414** perpendicularly positioned relative to longitudinal septum member **416** extending from extension member **420**, as described above. However, this variation may define a tapered edge **418** along the proximal edge of longitudinal septum member **416**. This tapered edge **418** may extend at an acute angle from extension member **420** towards transverse septum member **414** to facilitate removal of the septum assembly **412** from within the hollow body organ.

[0085] Another alternative on septum variations is shown in the perspective views of Figs. 21A and 21B. Ribbed septum assembly **430** may generally comprise transverse septum member **432**, longitudinal septum member **434**, tapered edge **440** extending between extension member **438** and transverse septum member **432**. However, the septum members **432, 434** may be ribbed **436** to facilitate collapse of the septum assembly **430** when withdrawn from the hollow body organ. The hardness and geometry of the septum assembly **430** may be accordingly configured to provide adequate strength during vacuum-assisted tissue acquisition yet flexible enough to collapse when removed from the patient. Fig. 21C shows one example of how collapse of the septum may be facilitated by withdrawing the septum into a receiving member **442** having a tapered opening **444**. As the septum assembly **430** is pulled into channel **446**, the ribbed surfaces may collapse into a smaller configuration for withdrawal.

[0086] Another alternative septum variation **450** is shown in the perspective view of Fig. 22A. Longitudinal septum member **452** may have at least two transverse septum members **454, 458** extending to opposite sides of longitudinal septum **452**. Each of the transverse septum members **454, 458** may define a helical tapered edge **456, 460**, respectively, such that removal of the septum assembly **450** from the hollow body organ is facilitated. Fig. 22B shows an end view of the septum assembly **450** positioned between pod members **462, 464**.

[0087] Rather than using a perpendicularly-configured septum, an alternative may be to utilize a septum member having only a longitudinally extending member which extends sufficiently

high so as to prevent cross-acquisition of tissue into the pod members. Fig. 23A illustrates an end view of an extendable septum assembly **470** positioned between pod members **472, 474** placed against stomach tissue **476**. Fig. 23B shows a side view of one variation for extending the septum assembly **478** from a low profile delivery configuration to an extended deployed configuration. Once septum assembly **478** has been advanced into a hollow body organ in its low profile configuration, the assembly **478** may be deployed into its expanded configuration. An extension septum member **480** may have a number of projections **482, 484** protruding from either side of extension **480**. A corresponding longitudinal septum base **486** may define channels **488, 490** through which projections **482, 484** located on extension **480**, respectively, may be translated within. Moreover, channels **488, 490** may be angled relative to a longitudinal axis defined by septum base **486** such that distally advancing extension **480** relative to septum base **486** raises extension **480** a distance away from base **486**, effectively increasing a height of the septum assembly **478**. Projections **482, 484** and channels **488, 490** may be covered so that travel of the extension **480** is uninhibited by surrounding tissue.

[0088] Similarly, Fig. 23C shows a side view of another septum assembly variation **492** in which extension septum member **494** is extendable from base septum member **496**. When advanced distally relative to longitudinal septum base **496**, extension **494** may travserse channels **498**, which form ramped channel portion **500**, defined within base **496** to extend into a septum assembly **492** having an increased height.

[0089] Fig. 24A shows another alternative septum assembly **510** which may be configured to deploy an extendable septum from a rolled-up configuration. As seen in the end view, septum assembly **510** is in a deployed configuration between pod members **512, 514**. Retractable septum **520**, may be extended from a rolled-up configuration within drum **516**, which may be positioned between opposing transverse septum members **518**. Cables **522** may extend from transverse septum members **518** for attachment to pod members **512, 514**. After the tissue has been acquired, retractable septum **520** may be retracted into drum **516** via manipulation of control cable **524**, as seen in Fig. 24B, to assume a low profile for withdrawal from the patient.

[0090] Another variation of septum assembly **530** is further shown in the perspective views of Figs. 25A and 25B. Septum assembly **530** may comprise transverse septum member **532** and collapsible septum member **534**, which may be configured between a collapsed configuration and an extended configuration. Transverse septum **532** may be elevated and lowered relative to pod members **548**, **550** during delivery and deployment of septum assembly **530**, e.g., via cross-members **536**, **538** which may be configured into a scissors-type mechanism. Cross-members **536**, **538** may have its proximal ends connected to control cable **542**, which may be routed through extension member **544**, while an intermediate portion of both cross-members **536**, **538** may be pivotally connected to one another via pivot **540**. Thus, articulation of control cable **542** from its proximal end by the surgeon or physician may actuate the scissors mechanism to either raise or lower transverse septum **532** in the directions of the arrow as shown. Transverse septum **532**, when positioned between pod members **548**, **550**, may be secured via cables **546**, as shown in Fig. 25B.

[0091] Figs. 25C and 25D show end views of transverse septum **532** and the collapsible septum member in an expanded or extended configuration **552** and in a collapsed configuration **554**. The collapsible septum member may be enclosed by a biocompatible material to prevent pinching of tissue by the cross-members **536**, **538**. Moreover, the material covering the collapsible septum may also be distensible, if desired. Various materials may be utilized, e.g., nylon, polymeric materials, woven materials made from various polymers, latex, elastomers, etc.

[0092] Figs. 26A to 26C show end, bottom, and perspective views of yet another alternative septum **560**. This particular septum **560** may be utilized with the device **340** of Figs. 16A to 16D. As shown, longitudinal septum **562** may be perpendicularly and integrally connected with transverse septum member **564** at one end and base septum member **566** at an opposing end of longitudinal septum **562**. Transverse septum member **564** may define radiused corners **568** at each of its four corners such that an atraumatic surface is presented to the tissue during use within a patient. Moreover, septum **560** may be extruded or formed from a singular piece of biocompatible material (any of the biocompatible materials suitable for such a structure as discussed herein may be utilized) such that a uniform structure is created.

[0093] Figs. 27A and 27B show perspective views of an alternative septum assembly **570** which may also be utilized particularly with the device **340** as discussed above. Fig. 27A shows septum **570** in a low profile delivery configuration where septum **570** may generally be comprised of two elongate T-shaped members. Each of the T-shaped members may be further comprised of longitudinal septum members **572, 572'** and transverse septum members **574, 574'**, respectively. Each of the two elongate T-shaped members need not be uniform with one another depending upon the device into which the septum assembly **570** is placed, but each member may be pivotally connected to one another via pivot **576** at a corner of adjacent longitudinal members **572, 572'**. Thus, during delivery of the device and septum **570** into the patient body, the low profile configuration of Fig. 27A may be maintained and prior to or during tissue acquisition and fixation, one of the members, e.g., septum members **572', 574'** may be pivoted in the direction of the arrow such that the longitudinal portions of the septum **572, 572'** contact one another to form an acquisition configuration **578** for the septum assembly, as shown in Fig. 27B. After tissue acquisition and fixation, the septum may be reconfigured into its low profile configuration for removal from the patient.

[0094] The septum in any of the above embodiments may be formed of a bioabsorbable and/or biocompatible material such as polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), polypropylene, polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, extruded collagen, silicone, polylactic acid (PLA), poly(lactic-co-glycolic acid) (PLGA), or polyglycolic acid (PGA). Furthermore, it may be flexible, biocompatible material which can either be left behind within the partition or expelled distally, and either absorbed within the stomach, or digested and expelled through the patient's gastrointestinal tract.

[0095] As discussed above, once the gastroplasty device has acquired the appropriate tissue, the device may be clamped upon the tissue to be fastened. Clamping multiple layers of tissue to one another may require a clamping mechanism which is configured to deliver a high degree of clamping pressure. One example of such a clamping mechanism **580** is shown in the perspective views of Figs. 28A to 28C, which show one variation for opening the clamp. Clamping mechanim **580** may have attachment members **582, 584** for secure connection to each of a pod member. Each

of the attachment members **582, 584** may be connected to one another via rotatable cams **586, 588**, where each cam may have a rotatable pivot, **590, 592**, respectively, protruding therefrom. Fig. 28A shows clamping mechanism **580** in a closed and clamped configuration while Fig. 28B shows the mechanism **580** being initially opened. To open (or close) the mechanism **580**, cam **586** may be rotated by actuating a control cable **600**, which may be routed, for instance, through a tubular member **596** positioned within the elongate member **12**, from its proximal end. Cam **588** may then be rotated by actuating control cable **602**, which may be routed within tubular member **598** also through tubular member **596**. Because attachment members **582, 584** rotate about pivot **590**, a channel **594** may be defined in member **582** within which pivot **592** may translate when cam **588** is rotated to effectuate clamping or opening of the pod members.

[0096] In addition to a cam mechanism **580**, clamping cables may also be utilized, as discussed above. Fig. 29A shows a perspective view of one example of how clamping cables may be routed through an acquisition and fixation device **610**. As seen, device **610** having pod members **612, 614** may be pivotable about longitudinal pivot **616**. Although a pivoting device is shown in this variation, the routing of cables may be utilized in any of the other acquisition and fixation devices utilizing pivoting motion as well as parallel clamping. A first clamping cable **620** may be routed into one of the pod members, e.g., pod member **614**, through positioning member **630** mounted on pod member **614** and routed over pulley or radiused member **622**, also contained within pod member **614**. First cable **620** may be looped **632** adjacent to pivot **616** to allow for placement of the septum (not shown for clarity) and then anchored to clamping cable anchor **618**. Likewise, second clamping cable **626** may be routed through positioning member **630** adjacent to first clamping cable **620** and through pod member **614** and over pulley or radiused member **628**, also contained within pod member **614**. Second cable **626** may also be looped **632** adjacent to pivot **616** to allow for placement of the septum and then anchored to clamping cable anchor **624**.

[0097] Fig. 29B shows a cross-sectioned end view of a parallel clamping device with the septum **634** shown. Like features are similarly numbered as corresponding features from Fig. 29A. As in the pivoting variation, first **620** and second **626** clamping cables may be routed through corresponding tubular members **640** and the cables may be looped through one or more slots **642** defined in septum **634** and subsequently routed into the opposing pod member for anchoring.

Clamping cables **620**, **626** are preferably routed to facilitate the unhindered translation of septum **634** as well as to ensure unobstructed access to openings **636**, **638** for the tissue to be acquired and fastened.

[0098] In yet another clamping variation, Figs. 30A and 30B show side and edge views of an alternative gastroplasty device **650** utilizing linked pod members. Cartridge member **652** and anvil member **654** may be connected to one another via linking arms **656**, **658** pivotally attached to one another via pivot **660** at one end of the device **650** and via linking arms **662**, **664** also pivotally attached to one another via pivot **666** at the opposite end of the device **650**. Clamping cables **672** may be routed through tubular member **670** into the device **650** and over pulleys **674**, **676**, as described above, for moving anvil member **654** between an open and closed configuration when acquiring tissue within acquisition region **668**. Firing cable **678** may be manipulated to deploy the fasteners from within cartridge member **652** when anvil member **654** is clamped over the acquired tissue. Deployment of the fasteners from cartridge member **652** may be achieved by incorporation of the firing wedge and other mechanisms as taught in U.S. Patent No. 4,610,383, which is hereby incorporated by reference in its entirety. In addition, clamping may be accomplished via hydraulic, pneumatic, or electropneumatic mechanisms, as discussed above.

[0099] In describing the system and its components, certain terms have been used for understanding, brevity, and clarity. They are primarily used for descriptive purposes and are intended to be used broadly and construed in the same manner. Having now described the invention and its method of use, it should be appreciated that reasonable mechanical and operational equivalents would be apparent to those skilled in this art. Those variations are considered to be within the equivalence of the claims appended to the specification.